



Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

Memorandum

Date May 5, 2000

From Jerome E. Dennis, Electronic Products Branch
DOE III, OC, CDRH

Subject Amendments to the Laser Standard – TEPRSSC Briefing Materials

To Dr. Orhan Suleiman

The materials consist of the draft of the amendments being developed for proposal and that tables of accessible emission limits that will be a part of the amendments to be proposed. The draft is still incomplete but is up to date as of this date. Tables still remain to be completed and then we will follow with an editorial review. The preamble presenting our rationale to the new elements of the proposal and the analysis of comments to the prior proposal remains to be written. The document is in a three-column format for ease of comparison between the present regulation, the amendments proposed in 1999 and the revision in process. Because of the complexity and sizes of their files, I have not included the tables that I have completed for the revision. We are retaining the structure and organization of the present CDRH standard since we have received many compliments over the years about its clarity.

Please make sure that the attached are drafts that represent our considerations at this time. They should not be considered as official. They can best be described as an attempt to incorporate some of the concepts from the Final Draft IEC standard into the format of the CDRH standard.

At its last meeting, TEPRSSC urged that we move with all due haste to make the requirements of our standard the same as those of the IEC standards (especially if it appears that the proposed amendments to the IEC 60825-1 will be approved), but that we should not adopt any of the IEC requirements that are unnecessarily restrictive or inappropriate, such as the expansion of the scope to include light emitting diodes (LEDs).

The new draft proposal does contain some new concepts based on inputs received over the last few years. These include:

- Redefinition of the criterion for human access to laser radiation that is only an ocular hazard to mean only the capability of direct eye exposure,
- Establishment of a class limit for laser products promoted or sold as toys or novelty items,
- Adoption of the new classifications, 1, 1M, 2, 2M, 3R, 3B and 4, of the IEC amendments,
- Incorporation into the standard of the existing requirement for specific authorization by the Department of Defense for lasers intended for combat, combat training or are

classified in national defense interests that may be exempted from certain requirements of the CDRH standard, and

- Revision of the requirements for service instructions to clarify that the intent of the requirement is limited to radiation safety procedures during servicing

The status of the amendments to IEC 60825-1 is that the Committee Draft for Vote (CDV) was approved with only one dissenting vote. The Technical Committee at its meeting in Milan in November approved issuance of a Final Draft International Standard (FIDS) for vote. That voting document is expected almost immediately. If approved as expected, the amended standard may be published in late August of this year.